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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/379,540	08/24/1999	SHLOMO BEN HAIM	BIO-76	1397

7590 05/27/2003

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EXAMINER	
GHAFOORIAN, ROZ	

ART UNIT	PAPER NUMBER
3763	17

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/379,540	Applicant(s) HAIM ET AL.	
	Examiner Roz Ghafoorian	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claim 1 is rejected under the judicially created doctrine of double patenting over claim1 of U. S. Patent No. 6309370 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an apparatus for inter-cardiac drug administration with a catheter having at least one position sensor which generates signals responsive to an applied field determining position and orientation coordination of the distal end of the catheter by generating signals responsive to the position of the distal end of the catheter within the heart; a drug delivery device which administers a desired dose of a therapeutic drug (i.e. cell) at the site determined responsive to the signals from the position sensor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-18, 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent 6321109 to Ben-Haim et al, and further in view of U.S Patent No. 6283951 to Flaherty et al.

Ben Haim teaches a system for intracardiac drug administration comprising a catheter, said catheter having at least one position sensor which generates signals responsive to an applied field for determining the position and orientation of the catheter, the singles being used to generate position and orientation coordinates, and a drug delivery device for delivering therapeutic material, the system also comprising control circuitry for determining position and orientation coordinates of a distal end of the catheter and foe generating a viability (functional) map of the hear comprising a site suitable foe targeted therapy by the catheter;(Col.5, lines 45-60)

Generating the viability map of the heart; identifying the site suitable for targeted therapy on the viability map; the heart camping a site suitable for targeted therapy by the catheter; inserting the catheter into a chamber of the heart at the site; delivering the therapeutic material to the site with the drug delivery device based on position and orientation coordinates in response to the signals form the position sensor. (Col.10, lines 5-15)

However Hamis does not teach an introduction of a cell. Flaherty discloses systems and methods that use the cardiovascular system as a conduit to deliver drugs, such as therapeutic drugs, genes, growth factors and the like, directly to selected tissue regions within the body. (Col.1, line 10-15) "Drug" as defined herein includes any therapeutic drugs, genetic materials, growth factors, cells, e.g. myocites, vectors carrying growth factors, and similar therapeutic agents or substances that may be delivered within a patient's body for any therapeutic, diagnostic or other procedure. In one aspect of the present invention, a transvascular catheter system is provided that generally includes a catheter, a drug delivery element, an orientation element, and possibly a puncturing element and/or an imaging element. (Col.3 line 54-62)

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combine the two teaching, according Flaherty therapeutic agents can be defined as cells, genetic materials, growth factors, cells.

3. Claims 1-18, 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent 6027473 to Ponzi and further in view of U.S Patent No. 6283951 to Flaherty et al.

Ben Haim teaches a system for intracardiac drug administration comprising a catheter, said catheter having at least one position sensor which generates signals responsive to an applied field for determining the position and orientation of the catheter, the singles being used to generate position and orientation coordinates, and a drug delivery device for delivering therapeutic material, the system also comprising control circuitry for determining position and orientation coordinates of a distal end of the catheter and foe

generating a viability (functional) map of the hear comprising a site suitable foe targeted therapy by the catheter;

Generating the viability map of the heart; identifying the site suitable for targeted therapy on the viability map; the heart camping a site suitable for targeted therapy by the catheter; inserting the catheter into a chamber of the heart at the site; delivering the therapeutic material to the site with the drug delivery device based on position and orientation coordinates in response to the signals form the position sensor.(Col.2, lines 10-25, 45-50)

However Hamis does not teach an introduction of a cell. Flaherty discloses systems and methods that use the cardiovascular system as a conduit to deliver drugs, such as therapeutic drugs, genes, growth factors and the like, directly to selected tissue regions within the body. (Col.1, line 10-15) "Drug" as defined herein includes any therapeutic drugs, genetic materials, growth factors, cells, e.g. myocites, vectors carrying growth factors, and similar therapeutic agents or substances that may be delivered within a patient's body for any therapeutic, diagnostic or other procedure. In one aspect of the present invention, a transvascular catheter system is provided that generally includes a catheter, a drug delivery element, an orientation element, and possibly a puncturing element and/or an imaging element. (Col.3 line 54-62)
Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combine the two teaching, according Flaherty therapeutic agents can be defined as cells, genetic materials, growth factors, cells.

4. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty, in view of U.S Patent No. 6321109 to Hamis or U.S Patent No. 6027473 to Ponzi in view of US Patent No. 6283951 to Flaherty, Further in view of German et al U.S Patent No.6258789.

Both Hamis and Ponzi in combination with Flaherty teach the above-mentioned invention except for treating the cells before introduction to the body. German discloses cells of a mammalian subject, which are genetically altered to operatively incorporate a gene, which expresses a protein, which has a desired effect. (Abstract). One of the objects of German's method is to produce genetically transformed cells (genetically superior cell), which have incorporated in the their genome exogenous genetic material in the form of a fully functional gene which expresses biologically active and therapeutically useful protein that functions with in the cell. (col.3, line 34-39) any exposure of the DNA of the treated cell to the immune system can result in adverse reaction such as inflammatory reactions to the DNA administered. (Col.2 lines 53-60) Therefore, it would be beneficial to treat these cells with immunosuppressants prior to implantation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have combines these teaching, because according to German simply expands on the origins of the cells in Flaherty and Gambale teachings.

Response to Arguments

5. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
May 6, 2003

Michael J Hayes

MICHAEL J. HAYES
PRIMARY EXAMINER